JUDGE BERMAN

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

13 CIV 3119

TED DAVISON, WILLIAM GOULD, AND RAY LENCI, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

vs.

VENTRUS BIOSCIENCES, INC., DR. RUSSELL H. ELLISON, DAVID J. BARRETT, and NATIONAL SECURITIES CORPORATION,

Defendants.

Civil Action No.

JURY TRIAL DEMANDED

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CLASS ACTION COMPLAINT

Plaintiffs, Ted Davison, William Gould, and Ray Lenci ("Plaintiffs"), allege the following based upon the investigation of Plaintiffs' counsel, which included, among other things, a review of Ventrus Biosciences, Inc.'s ("Ventrus" or the "Company") public documents, conference calls, and announcements made by Ventrus, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Ventrus, securities analysts' reports about the Company, and information readily available on the internet. Plaintiffs believe that substantial additional evidentiary support exists for the allegations set forth herein and will be available after a reasonable opportunity for discovery.

SUMMARY OF THE ACTION

1. This is a securities fraud class action brought on behalf of all persons who purchased or otherwise acquired the publicly traded common stock of Ventrus between December 17, 2010 and June 25, 2012 (the "Class Period"). This case is brought against Ventrus, its Chairman, Chief Executive Officer and Chief Medical Officer, Dr. Russell H. Ellison ("Ellison"), its Chief Financial Officer and Accounting Officer, David J. Barrett ("Barrett"), both of whom served as senior executives of Ventrus during the Class Period, and National Securities Corporation ("National Securities").[1] This action arises out of a fraudulent scheme and wrongful course of conduct whereby Defendants caused Ventrus to issue false and misleading statements to the investing public concerning the Company's lead product iferanserin VEN 309 ("VEN 309" or "iferanserin").

2. Ventrus is a development stage pharmaceutical company which focuses on late-stage prescription drugs for the treatment of gastrointestinal disorders, specifically, hemorrhoids,

[1] Defendants Ellison and Barrett are collectively referred to as the "Individual Defendants." Ventrus, Ellison, Barrett, and National Securities are collectively referred to as "Defendants."

anal fissures, and fecal incontinence.

3. VEN 309 is a topical treatment for hemorrhoids, which targets a specific serotonin receptor. The Company described VEN 309 as a new chemical entity for the topical treatment of symptomatic internal hemorrhoids. The Company stated that in seven clinical studies between 1993 and 2003, VEN 309 demonstrated good tolerability and no severe adverse events while showing statistically significant improvements in bleeding, itchiness, and pain.

4. In 2008, the Company began extensive discussions with the U.S. Food and Drug Administration ("FDA") under a Special Protocol Assessment, or SPA, process for the first U.S. clinical trial of VEN 309.

5. In connection with the FDA SPA process, on December 17, 2010, the Company issued its prospectus and registration statement for its Initial Public Offering ("IPO") of 2.9 million shares of common stock at $6.00 per share which were traded on the NASDAQ capital market under the symbol "VTUS." The Company stated that the primary use of the IPO proceeds would be to fund the clinical trial for VEN 309 and for the development of two other products.

6. National Securities Corporation ("National Securities") and Rodman & Renshaw, LLC, acted as co-lead underwriters for the IPO. National Securities is a subsidiary of National Holdings Corporation. According to the Company's IPO, National Securities is owned indirectly, through a controlling interest in Opus Point Partners, by Lindsay A. Rosenwald, a beneficial owner of approximately 31.9% of all outstanding shares of Ventrus common stock (making him Ventrus' largest stockholder). Thus, National Securities was presumed to have a "conflict of interest" with Ventrus under Financial Industry Regulatory Authority ("FINRA") Rule 2720.

7. On January 28, 2011, National Securities initiated analyst coverage of Ventrus. In an analyst report issued the same day, National Securities wrote:

> **Again, Bet The Horse, Bet The Jockey!** We know this management team very well and we trust in all things Ellison. We have worked with this [C]ompany for the past year and spent a lot of time with Dr. Ellison. His grasp on the science and drug development process is extraordinary, but we also have come to appreciate his Wall Street experience. . . . Investors familiar with Biotechnology investors know that companies with late stage productions (pivotal trends) tend to realize a significant inflection point towards data read outs. As such, we would not want to risk not being in the Ventrus story in advance of the trials' read-outs.

[Emphasis in original.]

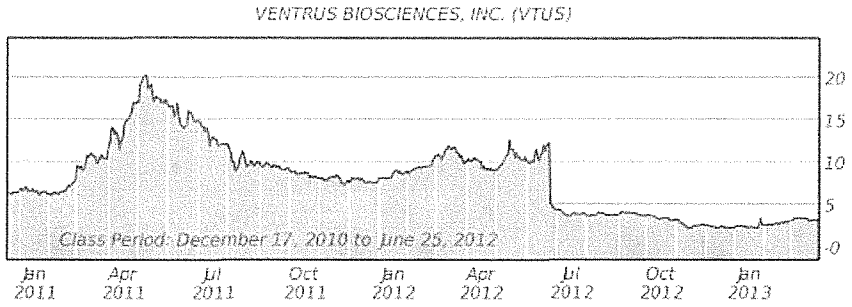
8. As described in detail below, throughout the Class Period, Defendants made a series of materially false and misleading statements touting the prospects and effectiveness of the Company's main and lead product – VEN 309. Specifically, the Company falsely represented that: (i) VEN 309 was a one-of-a-kind product that had no competing FDA approved products; (ii) VEN 309 would be the first and only product specifically approved for use as a prescription treatment for hemorrhoids; (iii) the prior phase II and IIB studies of VEN 309, including the prior Phase IIb German study, consistently demonstrated reduction of hemorrhoidal symptoms; (iv) the Company would be able to leverage VEN 309 to a market of over 12.5 million potential patients; and (v) the Phase III clinical trial for VEN 309 was "low risk" relative to most therapeutic drug development programs.

9. Specifically, during the Class Period, the Company touted its frequent and ongoing communications with the FDA, that clinical end points for the VEN 309 trial had been agreed to by the FDA, and that the prior results from Phase II and IIB trials of VEN 309 demonstrated the product's clinical efficacy. The Company specifically touted its frequent and ongoing communications with the FDA and its prior Phase IIb studies in Germany as evidence of VEN 309's efficacy to falsely support their claims that FDA approval would be achieved. These

false and misleading statements artificially inflated, maintained, and increased the price of Ventrus' common stock, reaching a high of $20.25 during the Class Period.

10. Defendants' representations further allowed the Company to raise over $70 million through two public offerings during the Class Period, including one approximately one month prior to revealing the truth concerning its Phase III clinical trial.

11. On June 25, 2012, Defendants shocked the market when it issued a press release announcing that VEN 309 failed its Phase III trial before the FDA, and that the Company would suddenly abandon further development of VEN 309, including any further attempt to obtain FDA approval. In response to this news, the price of Ventrus common stock plummeted over 50% – to $5.02 per share on June 25, 2012, resulting in millions of dollars in damages to Plaintiffs and the Class.



JURISDICTION AND VENUE

12. The claims asserted herein arise under §§10(b) and 20(a) of the Securities and Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§78j and 78t(a) and Rule 10b-5, 17 C.F.R. §240.10b-5. Jurisdiction is conferred by §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1331.

13. Venue is proper in this District pursuant to §27 of the Exchange Act, 28 U.S.C. §1391(b). Ventrus maintains its principal place of business in this District and many of the acts and practices complained of herein occurred in substantial part in this District.

14. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities market.

PARTIES

15. Plaintiff Ted Davison is a citizen of Florida. Plaintiff purchased Ventrus' publicly traded securities during the Class Period and was damaged thereby, as set forth in the Certification attached hereto.

16. Plaintiff William Gould is a citizen of Illinois. Plaintiff purchased Ventrus' publicly traded securities during the Class Period and was damaged thereby, as set forth in the Certification attached hereto.

17. Plaintiff Ray Lenci is a citizen of California. Plaintiff purchased Ventrus' publicly traded securities during the Class Period and was damaged thereby, as set forth in the Certification attached hereto.

18. Defendant Ventrus Biosciences, Inc. ("Ventrus" or the "Company"), is a Delaware corporation located and headquartered at 99 Hudson Street, 5th Floor, New York, New York 10013. Ventrus is a development stage pharmaceutical company, which is focused on late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures, and fecal incontinence. Ventrus' lead products are topical treatments for hemorrhoids, which targets a specific serotonin receptor. The Company's shares trade on the NASDAQ stock exchange under the symbol "VTUS."

19. Defendant Ellison is the Chairman, Chief Executive Officer, and Chief Medical Officer of Ventrus.

20. Defendant Barrett is the Chief Financial Officer and Accounting Officer of Ventrus.

21. Defendant National Securities is a broker-dealer located at 120 Broadway, 27th Floor, New York, New York. National Securities was the co-lead underwriter for the IPO.

BACKGROUND FACTS

22. In March 2008, Ventrus licensed iferanserin from Sam Amer & Co., Inc. ("Sam Amer"), which had previously been responsible for developing and advancing VEN 309 through Phase II trials and preparing the drug for its Phase III trials. In November 2011, Ventrus acquired the rights to iferanserin from Sam Amer for $12.5 million. In so doing, Ventrus reduced royalties by 66% and milestone payments from $20 million to $10.5 million.

23. Ventrus acquired the rights to ifernaserin to create VEN 309, a topical hemorrhoid treatment. The Company represented VEN 309 to be more effective and/or less invasive than the currently available over-the-counter conventional hemorrhoid topical therapies because of product's highly selective, antagonistic activity against peripheral 5-HT2 A receptors (5HT2 A>5HT2C>>5HT2B). The Company believed that by limiting 5-HT2 A receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness, and pain.

24. On July 20, 2010, the Company filed a Registration Statement with the SEC, on Form S-1, Number 333-168224, in which it announced its intention to hold an initial public offering for the sale of Ventrus common stock.

25. In this Registration Statement, Ventrus stated that it believed VEN 309:

> [T]o be more efficacious and/or less invasive than conventional hemorrhoid therapies. Iferanserin has selective, antagonistic activity against peripheral 5-HT2 receptors involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. ***By limiting 5-HT2***

> ***receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain.*** The potential for side effects is limited because iferanserin is topically applied. ***In multiple clinical trials, iferanserin ointment significantly reduced bleeding, pain and itchiness compared to placebo with minimal adverse effects.*** The development of iferanserin ointment has been completed up to the end of Phase II where the FDA has concluded that the product is ready to enter Phase III development. We also have filed a special protocol assessment, or SPA, with the FDA to ensure their explicit agreement with our Phase III clinical plan for VEN 309. We expect completion of the SPA process to occur in the fourth quarter of 2010 and to initiate Phase III trials by the first half of 2011.

[Emphasis added.]

DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

26. On December 17, 2010, the start of the Class Period, Defendants filed their Prospectus with the SEC on Form 424B4, and thereby commenced their initial public offering of 2.9 million shares of Ventrus common stock, at $6.00 per share. The Company anticipated that after underwriter fees and before other expenses associated with the offering were deduced, it would receive approximately $16.1 million from this offering.

27. The Company stated in its Prospectus that it had been in discussions via a series of emails and phone calls with the FDA in September 2010, and that it believed it had reached an agreement with the FDA on the precise definition of the endpoints for the VEN 309 trial. The Company represented that the agreement with the FDA was significant as it would allow the Company to utilize its prior results from its Phase II and Phase IIb studies in developing its Phase III study.

28. The Company further represented in the Prospectus that the prior Phase II studies demonstrated the product's efficacy:

> ***Phase II studies*** [conducted by Sam Amer] ***consistently demonstrate that ifernaserin treatment significant reduces hemorrhoidal symptoms of bleeding, itching and pain, and that the 0.5% concentration that we will be developing***

> ***was superior to lower concentrations and to higher concentration (1%) in the comprehensive reduction of hemorrhoid symptoms.***

[Emphasis added.]

29. Based on representations in the Prospectus, Ventrus stock spiked to $7.71 before closing on the first day of trading at $6.30.

30. On January 28, 2011, when National Securities initiated analyst coverage of Ventrus with a "Buy" rating, it wrote:

> The Company's wealth of Phase II data reduces risks around efficacy and safety which are further reduced by the nature of these therapeutics (topical administration). These proof of concept studies have demonstrated to us that the skew for the outcome on the pivotal trials is positive. The SPA (Special Protocols Assessment) further limits risk around the question of the first new therapeutics in these indications.

31. In this same analyst report, National Securities further wrote, "[i]n multiple clinical trials, Iferanserin cream significantly reduced bleeding, pain and itchiness compared to a placebo with minimal adverse effects."

32. National Securities added, "[t]he likelihood of FDA approval is high and the competitive landscape is favorable, with a large market and no other approved products. . . . [I]f approved, it is an attractive product for a large and underserved market." It then reiterated, "**Again, Bet The Horse, Bet The Jockey!**"

33. On March 18, 2011 the Company issued a press release where it stated that it had filed a revised protocol with the FDA under a Special Protocol Assessment (SPA) with new, more robust definitions for efficacy endpoints for VEN 309 that were recommended by the FDA in a recent meeting with the Company.

34. In the press release, in response to the FDA's recommended revisions, Ellison stated that the Company was: "'very pleased with the new endpoint definitions in that they

showed considerable differences between active drug and placebo in our analysis of an earlier Phase IIb study in Germany, which has been the cornerstone of our development program.'"

35. On May 2, 2011, the Company issued a press release stating that in response to the FDA's request, it had added a third treatment arm to its Phase III study of VEN 309.

36. In the press release, Ellison stated that the FDA's request was a positive signal for the Company:

> "When we analyzed our Phase IIB German study that compared Iferanserin given twice daily for 14 days, with placebo, using these endpoints, we observed that the majority of Iferanserin treated patients started their response by Day 3. ***This raises the possibility that Iferanserin therapy may require a shorter duration of treatment to show adequate efficacy to stop the bleeding, itching and pain associated with hemorrhoids***."

[Emphasis added.]

37. Ellison further stated: "It's not only good development practice to explore the possibility of a shorter treatment period as proposed by FDA's feedback, but should this regimen prove to be effective, it could be even more acceptable to patients."

38. Following the Company's press release and Ellison's positive statements contained therein, Ventrus stock shot up approximately 12% to close at $19.10 on May 3, 2011.

39. On May 11, 2011, ProActive Capital Group, an entity hired by Ventrus to provide capital market strategy services for the Company, issued a press release announcing that analyst Rodman & Renshaw recently more than doubled its price target from $12 to $25 per share for Ventrus. In touting VEN 309's development, ProActive stated that:

> ***Iferanserin ointment has a relatively <u>low risk</u> of clinical development based on a well established mode of action and the Phase 2b clinical trial results achieved in Germany, which provided the basis for the design and endpoints in the upcoming clinical trial.*** In addition, the treatment of hemorrhoids is currently based on over-the-counter (OTC), non-prescription products and there is no FDA-approved treatment for this very common condition. In addition OTC treatments such as Preparation H or Anusol do not address the underlying cause of

> hemorrhoids and merely treat the symptoms while Iferanserin works directly on the local blood vessels that result in the condition.

[Emphasis added.]

40. On June 22, 2011, the Company issued a press release whereby Ventrus announced that it had received a response from the FDA concerning its last SPA for VEN 309.

41. Specifically, the Company announced that the FDA had: "requested that additional information be included in the protocol pertaining to certain details of the trial. None of these new recommendations affect the previous recommendations made by the FDA for the endpoints, overall statistical powering and subject number, and the overall clinical design of the trial." Ventrus further stated that it agreed with the FDA's recommendations and would update its protocol accordingly.

42. In the press release, in response to the FDA's recommendations, Ellison stated:

> "***The Special Protocol Assessment process for our first pivotal trial with iferanserin (VEN 309) for the treatment of hemorrhoids has been very productive considering that this could be the first new drug application ever filed for a drug in this indication*** . . . ." "This process involved considerable work and thought at the FDA, and though we have not received a final agreement letter, we have implemented all of the suggestions and recommendations of the FDA on the major and important elements of the protocol, including, the definitions of the primary and secondary endpoints, overall design, regimens and doses, basic inclusion and exclusion criteria as well as overall statistical powering and the basic analysis methods. In addition, the definition of the endpoints that the FDA proposed referring to cessation, not just improvement of symptoms, and the addition the FDA proposed of the 7 day treatment arm, are important enhancements to our program. ***Given the substantial progress that we have made with the FDA in this process, we have decided to proceed with directly implementing our protocol with all FDA recommended changes without further pursuing the SPA.***

[Emphasis added.]

43. Thereafter, on July 14, 2011, the Company filed with the SEC its Prospectus in connection with its prior Registration Statement for the sale of approximately 5.1 million

additional shares of common stock at $10.00 per share. In the Prospectus, the Company reported positively concerning the status of the clinical trial for VEN 309: "***[s]even clinical studies of VEN 309 have been completed, and five of these studies demonstrated that VEN 309 significantly improved and in many cases eliminated the pain, bleeding and itching associated with hemorrhoids versus placebo ointment.***"

[Emphasis added.]

44. The Company further stated in July 14, 2011 Prospectus that it was no longer seeking FDA approval for the SPA but that it was continuing to proceed with the Phase III trials:

> ***Based on our clinical experience, we filed a Special Protocol Assessment, or SPA, with the FDA for our two proposed pivotal Phase III trials for VEN 309 for the treatment of hemorrhoids. During that process, we addressed all recommendations of the FDA to date including the definitions of the primary and secondary endpoints along with the other important design elements of the trial. However, we have determined to not further pursue the SPA so as not to delay the start of our planned Phase III trial for VEN 309 for the treatment of hemorrhoids.***

[Emphasis added.]

45. The Company further stated that as to its decision to discontinue seeking FDA approval for its SPA for VEN 309:

> ***We had filed an SPA with the FDA to ensure its explicit agreement with our first pivotal Phase III protocol for VEN 309, using the 0.5% dose. As part of that process, we have had extensive discussions with FDA about the protocol and filed a revised protocol on May 16, 2011. In late June 2011, the FDA issued its response and requested that additional information be included in the protocol pertaining to some details of the study, and therefore did not issue an agreement letter for the SPA.***

[Emphasis added.]

46. The Company, however, noted that its Phase III trials remained on track:

> ***None of these recommendations affect the previous recommendations of the FDA for the endpoints, overall statistical powering and subject number, and the***

> ***overall clinical design. We have incorporated these latest changes into the protocol and, in order to maintain our timelines for the trial, we intend to file the protocol to our existing IND with the FDA, and to not continue to pursue the SPA process.***

[Emphasis added.]

47. Additionally, the Company stated in the Prospectus that on June 5, 2011, it had entered into an agreement with Sam Amer to acquire all rights, title, and interest to VEN 309 for $500,000 plus an additional $12 million to be paid by November 15, 2011.

48. On August 15, 2011, the Company filed its Form 10-Q with the SEC where by it stated that the Phase III clinical trial for VEN 309 was on track:

> We have met with the FDA regarding our plans for the development of VEN 309, VEN 307 and VEN 308. We intend to initiate and conduct one of two pivotal Phase III clinical trials in the U.S. with VEN 309 beginning in the summer of 2011 and initiate a long term carcinogenicity study. Depending on our assessment of the data generated by the Phase III trial, which is expected in the first quarter of 2012, as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate, we intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial which, together with the first trial, a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit a new drug application, or NDA, to the FDA, which we anticipate could occur as early as 2014.

49. On Aug. 16, 2011 the Company issued a press release filed with the SEC via a Form 8-K whereby it announced that enrollment had opened for its first pivotal Phase III trial of VEN 309. The Company further announced that the Phase III trial of VEN 309 was been designed to include approximately 600 patients in a double-blind, 3-arm design. Iferanserin (0.5%) ointment was to be applied intra-anally twice per day, using a single-use tube and applicator and would be compared with matching placebo ointment.

50. Thereafter, on November 14, 2011, the Company filed its Form 10-Q with the SEC wherein it reiterated that the Phase III trial for VEN 309 was on track:

> We have met with the FDA regarding our plans for the development of VEN 309, VEN 307 and VEN 308 (phenylephrin). We initiated one of two pivotal Phase III clinical trials in the U.S. with VEN 309 in August 2011 and intend to initiate a long-term carcinogenicity study. Depending on our assessment of the data generated by the Phase III trial, which is expected in the first half of 2012, as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate, we intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial which, together with the first trial, a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit a new drug application, or NDA, to the FDA, which we anticipate could occur as early as 2014.

[Emphasis added.]

51. On November 14, 2011, the Company held a conference call with analysts during which Ellison confirmed that the Phase III trial for VEN 309 remained on track:

> NDA filing timelines for this product remain unchanged, inasmuch as these trials are not on critical path. In addition, ***the data quality is good. Good clinical research practice procedures are good. And I'm happy to say that no serious severe adverse events related to the drug have been seen to date.***

[Emphasis added.]

52. On November 14, 2011 the Company issued a press release concerning its top line results from the ongoing Phase III trial of VEN 309. The Company announced that it extended the timing to report the top line results from VEN 309 by approximately three months. As to the status of the clinical trials, Ellison again stated that the Phase III trials remained on track and progressing well:

> ***"Both trials [VEN 309 and VEN 307] are progressing well with respect to data quality and GCRP (Good Clinical Research Practices).*** As we expect to report top line Phase 3 results for both products in the second quarter of 2012, these milestones are likely to be close together in time . . . ." "Our projected NDA filing timelines for both VEN 309 and VEN 307 remain on track, and the new

> completion timelines for VEN 309 should have no material effect on the balance sheet."

[Emphasis added.]

53. The Company further reported that it had closed its acquisition of VEN 309 and touted the market research it had conducted into the commercial potential for VEN 309. Specifically, Ellison stated:

> "Given what we have discovered about the commercial potential of VEN 309, the progress of the development program, and what we have learned about the details of the regulatory pathway and the potential market and data exclusivity, we are very pleased to be able to finalize this transaction . . . ." "We believe that this could considerably enhance the value of this asset to the company."

[Emphasis added.]

54. On January 13, 2012, the Company issued a press release where it announced its prior Phase IIb study of VEN 309 was published in the peer reviewed journal Clinical Therapeutics.

55. The Company reported the Phase IIb study demonstrated clinical effectiveness of VEN 309:

> ***Compared with placebo, iferanserin [VEN 309] significantly reduced patient-reported severity of daily bleeding beginning at day 1 and itching beginning at day 2 ($P < 0.05$).*** The effects were sustained throughout the 14-day treatment period. There was also a reduction in patient-reported severity of daily pain seen with iferanserin treatment. Adverse events were mild and infrequent and did not differ significantly between treatment groups.
>
> [Emphasis added.]

56. The Company further stated that the publication presented an analysis of the endpoints used for the Phase III study and that the German Phase IIb study had demonstrated a satisfaction of those endpoints.

57. Specifically, the Company described the results of its German Phase IIb study:

> In the German Phase 2b study, it was determined that 57% of iferanserin-treated patients had cessation of bleeding versus only 20% of placebo-controlled patients (P = 0.0001). The secondary endpoints of the ongoing Phase 3 study are cessation of itching and pain by day 7 through day 14. In the German Phase 2b study, the data showed that 59% of iferanserin-treated patients versus 32% of placebo-controlled patients (P = 0.034) had cessation of itching, while pain ceased at day 7 and did not return by day 14 in 50% of iferanserin-treated patients versus 18% of placebo-treated patients (P = 0.032).

58. Ellison touted the significance of the results of the Phase IIb study, stating: "[t]he findings of this Phase 2b German trial were significant in defining the targeted patient population and developing meaningful endpoints for our ongoing pivotal Phase III trial for iferanserin. The therapeutic benefits observed in the Phase 2b trial suggest a potential role for iferanserin for the treatment of symptomatic hemorrhoids."

59. On March 14, 2012, the Company filed its Form 10-K with the SEC. Ventrus reported that its Phase III trial for VEN 309 continued on course and stated that its prior results for its Phase IIb trial demonstrated that VEN 309 "provided rapid and sustained improvements of the main symptoms of this disorder: bleeding, itching and pain." The Company further stated that the previous successful endpoints of the Phase IIb trial conducted in Germany would be used by the Company in conducting the parameters for the Phase III trial:

> We have modeled the potential performance of the primary and secondary endpoints which were proposed by the FDA and which we will be using in that trial, using data from the German Phase IIb trial, because the principal elements of the German Phase IIb trial are substantially similar to our first Phase III trial.

60. Moreover, the Company described the German Phase IIb results, which demonstrated statistical significance of VEN 309 over placebo:

> Applying the proposed statistical methodology and primary endpoint for our Phase III trial to the data from the German Phase IIb trial, the difference between the proportion of patients responding to treatment as defined by the new endpoint definition for cessation of bleeding in the VEN 309 arm (57% responders) and the placebo arm (20% responders) was considerable with $p < 0.0001$ (Figure 4). Similarly, analyses of the key secondary endpoints of pain and/or itching also

> showed considerable differences between VEN 309 and placebo (itching: 59% response to VEN 309 versus 32% response to placebo, $p < 0.034$; pain: 50% response to VEN 309 versus 18% to placebo, $p < 0.032$).

61. On April 30, 2012, Ventrus announced that it had completed patient enrollment for the first Phase III clinical trial. The Company disclosed that it expected to receive data in late June or early July 2012.

62. On May 9, 2012, the Company filed its requisite Form 10-Q with the SEC, in which it stated:

> Depending on our assessment of the data generated by the Phase III trial [for VEN 309], which is expected in late June or early July 2012, as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate, we intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial which, together with the first study, a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit a new drug application, or NDA, to the FDA and analogous filings to authorities in Europe and Japan, which we anticipate could occur in 2014.

63. On May 29, 2012, the Company filed its prospectus for a secondary offering of approximately 948,378 shares of common stock at a price of $10.24 per share.

64. The foregoing statements were false and misleading.

65. Throughout the Class Period, Defendants knowingly or recklessly misrepresented that the VEN 309 trial had a relatively low risk of failure based on a well established mode of action and the Phase IIb clinical trial results achieved in Germany, which provided the basis for the design and endpoints in the upcoming clinical trial.

THE TRUTH IS REVEALED

66. On June 25, 2012, Defendants stunned investors when they issued a press release, filed on Form 8-K with the SEC, in which they announced that the Company would stop

developing iferanserin (VEN 309), its topical hemorrhoid treatment, after the Phase III clinical trial found that 603 patients failed to improve when assessed for bleeding, itching, and pain.

67. Specifically, the Company disclosed in this press release that, "its Phase 3, randomized, double-blind, placebo-controlled clinical trial of iferanserin (VEN 309) in patients with hemorrhoidal disease did not meet its endpoints. . . . Results of this large, well-controlled study failed to demonstrate an improvement for therapy, in either treatment arm, over placebo for the primary and secondary endpoints."

68. Furthermore, in this June 25, 2012 press release, Defendant Ellison stated:

> We would like to thank both investigators and patients for their support and participation in this study and in the VEN 309 program. The outcome of our Phase 3 study comes as a surprise and a disappointment, particularly given the strong evidence of activity in our Phase 2 randomized study.

69. Ventrus also announced that it was abandoning the VEN 309 program. Specifically, the Company disclosed:

> While the Company intends to analyze the totality of its Phase 3 data further, it believes that current resources would be better allocated toward the planned completion of its VEN 307 (diltiazem cream) development program in anal fissures and the beginning of further development of VEN 308 (topical phenylephrine) in fecal incontinence. Consequently, Ventrus has no immediate plans to continue development of VEN 309, resulting in a reduction in expenses.

70. When the truth about the Phase III study was revealed to the investing public, the stock price plummeted, falling from $12.26 on June 22, 2012 to just $5.02 on June 25, 2012. This represented a one day stock drop of approximately ***fifty-nine*** percent on heavy trading volume.[2] The stock has not recovered, and is presently trading at less than $3 per share at the time of the filing of this Complaint.

[2] June 22, 2012 was a Friday and the truth was disclosed on Monday, June 25, 2012, so this precipitous stock decline occurred on one day of trading.

LOSS CAUSATION/ECONOMIC LOSS

71. During the Class Period, Defendants engaged in a scheme and wrongful course of conduct pursuant to which they made false and misleading statements concerning the Company's iferanserin product and the Phase III study for VEN 309. Defendants' actions artificially inflated the price of Ventrus securities and operated as a fraud and deceit on Class Period purchasers of Ventrus' securities. When the impact of Defendants' fraudulent conduct was disclosed to the market, Ventrus' stock price fell precipitously as the artificial inflation created by Defendants' misrepresentations and wrongful course of conduct came out of the Company's stock price. As a result of their purchases of inflated Ventrus securities during the Class Period – and the subsequent decline in the price of those securities – Plaintiffs and other members of the Class suffered damages under the federal securities laws.

72. Defendants' conduct was designed to, and did, cause Ventrus securities to trade at artificially inflated levels throughout the Class Period, with Ventrus' stock price reaching as high as $20.25 per share on May 9, 2011. That inflation was removed from Ventrus' securities following the June 25, 2012 disclosure when Ventrus finally revealed the truth about its Phase III study regarding iferanserin, VEN 309, including the failures of the Phase III study and the Company's decision to abandon VEN 309. Indeed, the stock price declined substantially from a closing price of $12.26 on June 22, 2012, to just $5.02 on June 25, 2012. This represented a one day drop of approximately ***fifty-nine*** percent. Moreover, the stock has not recovered, and is presently trading at less than $3 per share at the time of the filing of this Complaint.

73. The price decline in Ventrus common stock was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the decline in the price of Ventrus common stock in response to this revelation

negates any inference that the loss suffered by Plaintiffs and other Class members was caused by changed market conditions, macroeconomic issues, industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct.

74. The damages suffered by Plaintiffs and other members of the Class were a direct result of: (a) Defendants' fraudulent scheme to artificially inflate the price of Ventrus common stock during the Class Period; and (b) the subsequent significant decline in the value of Ventrus common stock when the impact of Defendants' prior misrepresentations and other fraudulent conduct became known to the market.

APPLICABILITY OF PRESUMPTION OF RELIANCE, FRAUD-ON-THE-MARKET DOCTRINE

75. At all relevant times, the market for Ventrus' publicly-traded securities was an efficient market for the following reasons, among others:

a. Over 12.4 million shares of Ventrus common stock was issued and outstanding during the Class Period and were listed and actively traded on the NASDAQ stock exchange, which is a highly efficient and automated market;

b. As a regulated issuer, Ventrus filed periodic public reports with the SEC and the NASDAQ;

c. Ventrus regularly communicated with public investors via established communication mechanisms, including through regular disseminations of press releases on major national news wire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d. Ventrus was followed by numerous securities analysts employed by brokerage firms, including National Securities, Cantor Fitzgerald & Company, William Blair & Company, Rodman & Renshaw, Inc., Stonegate Securities, and Brean Capital, LLC, who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

76. As a result of the foregoing, the market for Ventrus' publicly traded securities promptly digested current information regarding Ventrus from all publicly available sources and reflected such information in the prices of Ventrus' publicly traded securities. Under these circumstances, all purchasers of Ventrus' publicly traded securities during the Class Period suffered similar injury through their purchase of Ventrus' publicly traded securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR EXISTS FOR DEFENDANTS' STATEMENTS

77. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as "forward-looking statements" when made or were not accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false, forward-looking statements because at the time each of those forward-looking statements was made, the speaker knew that the particular forward-looking statement was false, and/or the forward-looking

statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

CLASS ACTION ALLEGATIONS

78. Plaintiffs bring this action as a class action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of all persons who purchased or otherwise acquired Ventrus publicly traded common stock during the Class Period (the "Class"). Excluded from the Class are Defendants and members of their families, directors and officers of the Company, and their families and affiliates.

79. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Ventrus had more than 12.4 million shares outstanding, owned by thousands of persons.

80. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class, which predominate over questions that may affect individual Class members, include:

a. whether Defendants violated the securities laws;

b. whether Defendants caused statements to be disseminated which omitted and/or misrepresented material facts;

c. whether Defendants caused statements to be asserted which omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. whether Defendants' conduct caused Plaintiffs and the Class to suffer damages; and

f. if so, the proper measure of damages.

COUNT ONE

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against Ventrus and the Individual Defendants)

81. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

82. During the Class Period, Defendants participated in the preparation of, and/or caused to be disseminated, the false statements specified above, which they knew or recklessly disregarded were materially false and misleading in that they contained material misrepresentations and failed to disclose material facts necessary to render the statements made, in light of the circumstances under which they were made, not misleading.

83. Defendants violated §10(b) of the Exchange Act and SEC Rule 10b-5 in that they:

a. employed devices, schemes, and artifices to defraud;

b. made untrue statements of material fact or omitted to state material facts necessary to render the statements made, in light of the circumstances under which they were made, not misleading; and/or

c. engaged in acts, practices, and/or a course of conduct that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Ventrus securities during the Class Period.

84. Defendants, individually and together, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a

continuous course of conduct to conceal the truth and/or adverse material information about the business, operations, and future prospects of Ventrus as specified herein.

85. These Defendants employed devices, schemes, and artifices to defraud, while in possession of material, adverse, non-public information and engaged in acts, practices, and a course of conduct as alleged herein by, among other things, participating in the making of untrue statements of material fact and omitting to state material facts necessary to render the statements made about the Company and its business operations, including the potential for VEN 309, in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Ventrus securities during the Class Period.

86. Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them. Defendants knowingly, or with reckless disregard for the truth falsely represented that: (i) VEN 309 was a one-of-a-kind product that had no competing FDA approved products; (ii) VEN 309 would be the first and only product specifically approved for use as a prescription treatment for hemorrhoids; (iii) the prior phase II, and IIB studies of VEN 309, including the prior Phase IIb German study consistently demonstrated reduction of hemorrhoidal symptoms; (iv) the Company would be able to leverage VEN 309 to a market of over 12.5 million potential patients; and (v) the Phase III clinical trial for VEN 309 was "low risk" relative to most therapeutic drug development programs.

87. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Ventrus' publicly traded securities was artificially inflated during the Class Period. In ignorance of the fact that the

market prices of the Company's publicly traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements, and/or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and other members of the Class acquired Ventrus securities during the Class Period at artificially high prices and were damaged thereby, as demonstrated, in part, by the declines in the price of the Company's stock following the June 25, 2012 revelations of truth discussed herein.

88. At the time of these misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiffs, the other members of the Class, and the marketplace known the truth as alleged herein, which was not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Ventrus common law, or, if they had purchased or otherwise acquired these securities during the Class Period, would not have done so at the artificially inflated prices that they paid.

89. By virtue of the foregoing, Defendants have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

90. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Ventrus common stock during the Class Period.

COUNT TWO

Violations of Section 20(a) of the Exchange Act
(Against the Individual Defendants and National Securities)

91. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

92. The Individual Defendants acted as controlling persons of Ventrus within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, participations in and/or awareness of Ventrus' operations, and/or intimate knowledge of the false statements disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Ventrus, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's press releases and other statements alleged by Plaintiffs to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

93. In particular, each Individual Defendant had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein and exercised the same.

94. As set forth above, these Individual Defendants violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint.

95. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendants'

wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of Ventrus common stock during the Class Period.

96. This action was filed within two years of discovery of the fraud and within five years of Plaintiffs' purchases of securities giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action by certifying it under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such equitable, injunctive, or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

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